AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,915	09/05/2003	Alan D. Attie	960296.99080	8862

7590 10/21/2005

Nicholas J. Seay
Quarles & Brady LLP
P O Box 2113
Madison, WI 57301-2113

EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,915	ATTIE ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, in part drawn to a method of determining susceptibility to type 2 diabetes by determining the SorCS1 allele of a subject using nucleic acid based methods, classified in class 435, subclass 91.1.

II. Claims 1-3, in part drawn to a method of determining susceptibility to type 2 diabetes by determining the SorCS3 allele of a subject using nucleic acid based methods, classified in class 435, subclass 91.1

III. Claim 4, in part drawn to a method of determining if a human being is a candidate for developing type 2 diabetes by determining the mRNA expression of the SorCS1 gene, classified in class 435, subclass 6.

IV. Claim 4, in part drawn to a method of determining if a human being is a candidate for developing type 2 diabetes by determining the mRNA expression of the SorCS3 gene, classified in class 435, subclass 6.

V. Claim 4, in part drawn to a method of determining if a human being is a candidate for developing type 2 diabetes by determining the protein expression of SorCS1, classified in class 435, subclass 7.1.

VI. Claim 4, in part drawn to a method of determining if a human being is a candidate for developing type 2 diabetes by determining the protein expression of SorCS3, classified in class 435, subclass 7.1.

VII. Claims 5-6, drawn to a method for identifying an agent that interacts with SORCS1 protein, classified in class 436, subclass 501.

VIII. Claim 7, drawn to a method of treating type 2 diabetes by administering neurotensin, classified in class 514, subclass 2.

IX. Claim 8, drawn to a method of detecting a therapeutic agent by determining if a test agent modulates the biological activity of the SORCS1 protein, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of groups I, III, V, VII and IX are patentably from the methods of groups II, IV, and VI as they are drawn to methods of using SorCS1 nucleic acids or proteins which are structurally and functionally distinct from SorCS3 nucleic acids and polypeptides used in groups II, IV, and VI. Further, the methods utilizing SorCS3 are unobvious over methods utilizing SorCS1. A search burden exists for searching more than one of the patentably distinct groups because art relating to SorCS1 diagnostics or therapeutics will not necessarily provide any information regarding SorCS3 and vice versa.

The methods of groups I-VII and IX are patentably distinct from each other because the methods require different steps and have different modes of operation. Methods of detecting genetic alterations of groups I and II require structural analysis of nucleic acids and therefore requires different reagents, reaction parameters and reaction conditions than methods of detecting nucleic acid expression or protein expression of groups III-VI, which requires a determination of the quantity of mRNA or protein. The methods of nucleic acid expression are distinct from those analyzing protein expression as they require detection of structurally and

functionally distinct molecules. Additionally, the level of a nucleic acid's mRNA expression is not necessarily predictive of protein expression. Additionally, such methods require different reagents, reaction parameters and conditions than the methods of screening of group VII which requires detection of a test agent that binds to SORCS1 protein or the methods of identifying a therapeutic agent of group IX which requires testing for modulation of SORCS1 protein biological activity. The methods are unobvious over one another and a search burden exists for searching more than one of the patentably distinct inventions. Art relating to genetic alterations will not necessarily provide any information regarding nucleic acid expression or protein expression, or art relating to agents that bind to SORCS1 protein or modulate it's biological activity.

The inventions of groups I-VII and IX are unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of group VIII, drawn to treatment using neurotensin has different modes of operation, different functions, and different effects than the methods of diagnosis of groups I-VI and the methods of screening of groups VII and IX.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for one group is not required for any other group, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634
10/17/05